Remarks

Claims 24-39 are pending in the application and are presented for the Examiner's review and consideration. Claims 17-23 have been cancelled and claims 24-39 have been added. Applicant believes the claim cancellation, additions, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

§112 Claim Rejections

Claims 17 and 19 were rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 17 and 19 have been cancelled rendering the rejection of these claims moot.

§ 103 Claim Rejections

Claims 17-23 were rejected under 35 U.S.C. §103(a) as being anticipated by U.S. Patent No. 6,669,482 to Shile ("Shile") in view of U.S. Patent No. 6,058,322 to Nishikawa et al. ("Nishikawa"), in view of U.S. Patent No. 6,551,107 to Buckley et al. ("Buckley"), as applied in the previous Office Action, and in further view of U.S. Patent No. 6,260,021 to Wong et al. ("Wong") and in further view of U.S. Patent No. 5,819,288 to De Bonet ("De Bonet").

Claims 17-23 have been cancelled rendering the rejection of these claims moot.

New Claims

Claims 24-39 have been added. Applicant respectfully submits that these claims are patentable over the cited references for the following reasons.

Shile discloses a training method for improving diagnostic accuracy and reducing variability in the interpretation of radiologic exams. (Abstract). The method of Shile includes use of standardized terminology during interpretation of radiologic studies to characterize image findings. (Col. 1, lns. 19-22).

In accordance with Shile, generally stated, a training method is described by which a radiologist's or other exam interpreter's ability to interpret radiologic studies of a patient, whether presented on film, or in a digital format is measured. (Col. 4, ln. 64 – Col. 5, ln. 1). The method requires that trainees interpret a set of mammograms so that data can be collected. (Col. 5, lns. 61-62).

With respect to the datasets, a first set is representative of the screening environment and is collected from consecutive cases read in a screening practice or group of practices, or by sampling cases from a screening program or group of programs. (Col. 6, lns. 53-57). The sampling produces exams representative of those obtained from a screening referred population. (Col. 6, lns. 57-58). However, since many women undergoing screening mammography have no breast pathology, this dataset should include only those exams that demonstrate findings. (Col. 6, lns. 59-61).

A second test set consists of cases referred from screening mammography for diagnostic evaluation. (Col. 7, lns. 11-12). Exams for this test set should be collected from consecutive cases referred for diagnostic work-up from a screening mammography practice or group of practices. (Col. 7, lns. 15-18). Only cases with confirmed findings are included in this data set. (Col. 7, lns. 22-23).

A third image test set consists of mammograms from patients referred for biopsy. (Col. 7, lns. 35-36). During interpretation sessions with a test set, it may be useful to have findings on exams in the test set clearly identified. (Col. 7, lns. 50-52).

Image interpreters interpret each exam by using BI-RADS feature descriptors to describe each of the findings identified in an exam. (Col. 8, lns. 52-54). For each such finding the interpreter provides an assessment concerning the presence of malignancy. (Col. 8, lns. 54-55). All of the exam images are interpreted in the same manner, and testing is complete when all the images have been interpreted. (Col. 8, lns. 61-63). After interpretation is completed, performance values are calculated. (Col. 9, lns. 7-8).

Performance data along with exam images, patient data, and response data are sorted and grouped for feedback to the image interpreter. (Col. 9, lns. 24-26). Feedback sessions enable image interpreters to review their use of feature descriptors and to better understand the

relationships between individual or groups of descriptors and known biological processes imaged in the mammographic examinations. (Col. 9, lns. 63-67).

As such, Shile discloses a method for training a viewer in the interpretation of radiologic exams. The training method uses a dataset of exam images, with the dataset broken down into three test sets. The first test set includes only exams that have demonstrated findings, these can be either benign or malignant findings. The second test set consists of cases referred for diagnostic evaluation. Again, only cases with confirmed finding are included in the second test set. The third test set consists of mammograms from patients referred for biopsy. As such, this test set also only includes images with confirmed findings.

Upon completion of viewing the images of the dataset, the interpreter's diagnostic results are evaluated against the known results to determine the interpreter's diagnostic accuracy. Feedback sessions are provided to review the interpreter's results and use of the feature descriptors.

As noted above, Shile's training method only uses exam images with known results. The use of exam images with unknown results is explicitly taught against, and would in fact defeat the purpose of training, namely, in providing feedback on the interpreter's diagnostic results and use of feature descriptors.

Furthermore, the Shile method is only a training method for increasing an interpreter's accuracy and training the interpreter in the use of description features. Shile fails to disclose, suggest, or provide motivation that the method can be used for in-service monitoring of an interpreter during the viewing cases with unknown results, i.e., real cases that have yet to be diagnosed. In fact, Shile specifically teach against this, requiring that the dataset include only case with known results. The inclusion of Nishikawa, Buckley, Wong, and De Bonet fails to overcome the deficiencies of Shile.

In contrast, the present invention relates to a method and system for in-service monitoring and training for a radiologic workstation. (Page 1, lns. 21-22). For the purposes of in-service radiologist's performance monitoring of a real screening session, the session preparation by means of the session preparation module 18 is typically done by a super user and not by the radiologist who actually performs the screening operation. (Page 9, lns, 1-4)

For a particular user the case stack 7 is initialized to contain the cases to be reviewed by that user as well as a certain profile of known cases to be inserted into the flow of images. (Page 9, lns. 7-9). When the user starts the screening procedure the program 10 obtains a pseudo-random number from the pseudo-random number generator 11 in order to decide whether the real case i to which the pointer 8 points is to be displayed or if a known case is to be displayed. (Page 9, lns. 13-16). In the case of a known case the diagnosis is compared to the ground truth and/or pathology. (Page 9, lns. 26-27). If a mismatch between the diagnosis and the ground truth and/or pathology occurs, this is recognized by the program 10, and a corresponding message is displayed on the monitor 20. (Page 9, lns. 27-29). For example the message can be "you missed a cancer" or similar. (Page 9, lns. 29-30). At the end of the screening or training session a report can be generated based on the contents of the user action database 23 in accordance with the rules 24. (Page 10, lns. 13-15).

As such, the present invention discloses an in-service monitoring system and method which monitors the user's accuracy as they view a case stack. The case stack includes real cases, i.e., cases that have yet to be diagnosed, which are viewed and diagnosed by the user. To monitor the user's accuracy, known cases, i.e., cases with known results, are inserted into case stack for viewing and diagnosis of the user. The user's diagnosis of the known case is compared to the known results, and if incorrect the user is informed of the incorrect diagnosis. The incorrect diagnosis is also noted for generation of a report upon completion of the case stack.

As previously discussed, Shile fails to disclose, suggest, or provide motivation for inserting known cases into a case stack of real cases to monitor a user. Furthermore, the inclusion of Nishikawa, Buckley, Wong, and De Bonet fail to overcome the deficiencies of Shile.

Independent claim 24 recites, *inter alia*, a computer system for in-service monitoring of a user screening medical cases. The computer system includes a case stack of real cases to be reviewed by the user and a library of known cases. A user interface component is included for requesting a consecutive case, for display of the consecutive case, and for entering a diagnosis of the consecutive case. A program component for receiving a request for the consecutive case from the user interface is included, where the program component selects the consecutive case from the case stack of real cases or the library of known of cases for the display and the

diagnosis. A feedback component for outputting a message to the user if the user diagnosis of a selected known case is incorrect is also included. Claims 31 and 39 includes similar elements.

In light of the foregoing, independent claims 24, 31, and 39 are respectfully submitted to be patentable over the cited references. As claims 25-30 depend from claim 24 and claims 32-38 depend from claim 31, these dependent claims include all of the elements of their base claims. Accordingly, Applicant respectfully submits that the dependent claims are in condition for allowance at least for the same reasons.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $395.00 is believed to be due for the filing of this Request for Continued Examination "RCE". The fee is being paid electronically via the Electronic Patent Filing System (EFS). Please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 739-X01-004).

Respectfully submitted,

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